



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Morris Samelson and
Johnathan M. Scharff
Serial No.: 10/601,796
Filed: June 23, 2003
For: **Ultra Fine Dead Sea Mineral Compound and Method of Manufacture**
Group No.: 1615
Examiner: Lakshmi Sarada Channavajjala

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop: RESPONSE/FEE Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, on August 23, 2007.

MORRIS SAMELSON

(Printed or typed name of person signing the certificate)

M. Samelson

(Signature of the person signing the certificate)

**DECLARATION OF PRIOR INVENTION IN THE UNITED STATES TO OVERCOME
CITED PATENT OR PUBLICATION (37 C.F.R. § 1.131)**

1. This declaration is to establish completion of the invention of the above referenced United States Patent application ("Application") in the United States at a date before May 7, 2001, the earliest priority date of prior art application serial US 2003/0211062 ("Laden") that was cited by the Examiner.

2. The person making this declaration is the inventor.

Facts and documentary evidence

3. To establish a date of conception of the invention of this application before the priority date of Laden, the following attached documents are submitted as evidence, all of which are true copies of the originals:

- (i) Manufacturing Batch Record Compounding Module dated February 2, 2001.
- (ii) Manufacturing Batch Record Milling Module dated February 1, 2001.
- (iii) Photos of the finished product PharmaSea® Dead Sea Mineral Scrub showing front and back silk screened labeling as well as product lot number stamped into tube corresponding to date of manufacture.
- (iv) Drawings summarizing invention dated December 2006.

4. Laden is a national stage entry of application No. PCT/US01/14570 which was filed on May 7, 2001 and claims priority to an earlier filed provisional application 60/202,409 which fails to disclose the present invention found in Application. Laden was published on November 13, 2003. Laden teaches anhydrous skin cleansers with abrasive materials. The divisional Application was filed on June 23, 2003 and claims priority to filing date August 16, 2001 less than four months after Laden's earliest priority filing date of May 7, 2001.

5. The Applicant avers the following:

- (a) Applicant conceived the invention before February 2, 2001;
- (b) For a period of approximately one year prior to August of 2000 we had experimented extensively with selected natural ingredients and attempted to include the native Dead Sea minerals but were unable to find a suitable formulation due to the larger granules sizes. Extensive research and development utilizing processed ultra fine Dead Sea minerals (salts) was carried out during the six months prior to January of 2001 in order to develop the processor necessary to process native Dead Sea minerals into ultra fine Dead Sea minerals as novel commercially viable raw material ingredients for esthetically acceptable formulations. The

purpose of the final experimentation in January 2001 (for which charts have been previously submitted to file) was to re-evaluate our findings and determine the final formula best suited as our consumer product PharmaSea® Dead Sea Mineral Scrub product which includes our processed ultra fine Dead Sea minerals having granularity 100% less than 1 mm.

(e) The Application was filed on June 23, 2001 and is a divisional of application 09/931,453 filed on August 16, 2001.

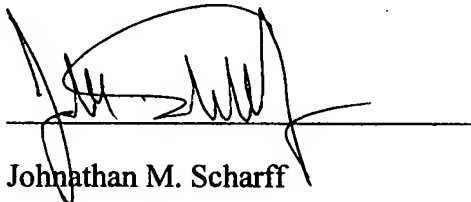
6. From these documents and photos, it can be seen that the invention in the Application was reduced to practice by February 2, 2001 which is earlier than the priority date of Laden.

7. The foregoing also establishes the diligence of the Applicant, from the time of conception to the time of constructive reduction to practice.

8. Information of further relevance was included in and attached to my previous Declaration under 37 C.F.R. § 1.132 dated January 16, 2007 and submitted to file.

9. This declaration is submitted in response to an office action in which Examiner relied on Laden as a reference.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.


Johnathan M. Scharff

8/23/07
Date

(ATMOSULTRAMILL) MILLING MODULE

ISSUED

- ☒ Preparation
- ☒ Description Pages
- ☒ Bulk Milling

REVIEWED

- ☒ Preparation
- ☒ Description Pages
- ☒ Bulk Milling

Issued By: MORRIS SAMELSON
Date: 02/01/01

Reviewed By: JOHNATHAN M. SHARFF
Date: 02/01/01

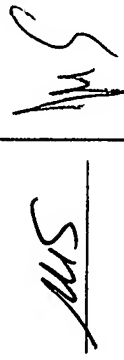
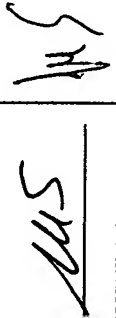


Prepared By: <u>M. Samelson (MS)</u>	Date: <u>02/01/01</u>	Module: <u>Milling</u>	Page: <u>1</u> Of: <u>7</u>
Approved By: <u>[Signature]</u>	Date: <u>02/01/01</u>	Raw Material Name: <u>Processed ULTRA FINE Dead Sea Minerals (salts)</u>	

					Performed By:	Verified By:		
<p style="text-align: center;"><u>PREPARATION</u></p> <p>I. <u>Equipment Required</u></p> <p>a. Primary milling system: Modified Conical Screen Mill Hapman infeed conveyor (infeed to milling system) Hapman outfeed conveyor (for drum fill on weigh scale) Dust control system, Mettler floor scale, wench</p> <p>II. <u>Preliminary Work</u></p> <p>a. Batch DOES NOT require QA release prior to milling.</p> <p>III. <u>Safety Precautions</u></p> <p>a. Eye protection must be worn during entire manufacturing process. Dust control system must be attached and activated prior to and during milling process. All electric controls to be checked prior to plug in of systems with all switches in off position.</p> <p>THE ABOVE SAFETY PRECAUTIONS HAVE BEEN READ, UNDERSTOOD, SIGNED AND DATED BELOW:</p> <p><u>M. Samelson</u> _____ <u>02/01/01</u> _____ <u>02/01/01</u> _____ <u>02/01/01</u> _____</p> <p>Prepared By: <u>M. Samelson</u> Module: <u>Milling</u> Page: <u>2</u> Of: <u>7</u> Section: <u>Preparation</u> Page: <u>1</u> Of: <u>1</u> Document No. <u>M001.001.00</u> Approved By: <u>M. Samelson</u> Product Name: <u>Processed ULTRA FINE Dead Sea Minerals (salts)</u> Lot Code: <u>20101AUM</u> (Include date)</p>							<p style="text-align: center;">MS</p>	

Earth Salts International Inc. Manufacturing Batch Record Date of Manufacture: February 1, 2001

Part Number	Description of processed raw material produced in house	Amount needed	Amount Weighed	Performed By:	Checked By:	
	PROCESSED RAW MATERIAL					
2001	(Processed) ULTRA FINE Dead Sea Salts	910 Lb	906	<i>MUS</i>	<i>MUS</i>	
	Size: 100% less than 1 mm and 10 mesh US Sieve unit.					
	Suitable for use in manufacturing products that require scrubbing effect as well as those that do not require scrubbing effect. (Grade 1)					
	<p>Action: 910 Lb native Dead Sea minerals (salts) processed through proprietary ATMOSULTRAMILL system with modified room atmosphere with temperature 75°F with cool dry positive pressure. RPM 4800. Material Choke fed. Native Dead Sea Salts have been processed into ULTRA FINE Dead Sea Salts. Native Dead Sea Salts information attached including Typical Analysis.</p>					
Prepared By:	<i>MUS</i>	Module: Milling	Page: Of: 3 7	Section: Description	Page: Of: 1 2	Document No. M001.000.00
Approved By:	<i>MUS</i>	Raw Material Name: Processed ULTRA FINE Dead Sea Minerals (salts)				Lot Code: 20101AUM

Part Number	Description of processed raw material produced in house	Amount needed	Amount Weighed	Performed By:	Checked By:		
	PROCESSED RAW MATERIAL						
2002	(Processed) ULTRA FINE Dead Sea Salts	110 Lb	108	MS	MS		
	Size: 100% Less than 1 mm and 10 mesh US Sieve unit.						
	Suitable for use in manufacturing products that require scrubbing effect as well as those that do not require scrubbing effect. (Grade 2)						
	110 Lb native Dead Sea minerals (salts) processed through proprietary ATMOSULTRAMILL system with modified room atmosphere with temperature 75°F with cool dry positive pressure. RPM 4800. Change part for finer material. Material choke fed. Native Dead Sea Salts have been processed into ULTRA FINE Dead Sea Salts. Native Dead Sea Salts information attached including Typical Analysis.						
Prepared By:	Module: Milling	Page: 4	Of: 7	Section: Description	Page: 2	Of: 2	Document No. M001.000.00
Approved By:	Raw Material Name: Processed ULTRA FINE Dead Sea Minerals (salts)						Lot Code: 20101AUM

Grade 1:				Performed By:	Verified By:
<p align="center"><u>BULK MILLING</u></p> <p>I. Connect Hapman conveyors to mod. conical screen mill with attached dust control and Metler floor scale for weigh activated filling of fiber drums with 4 mil inner liner bags (lock tied) forming ATMOSULTRAMILL: Activate system (turn on all components) and begin adding native Dead Sea Salts to in-feed hopper as needed to maintain steady fill rate on drums.</p> <p align="center"><u>ADDED</u> Native Dead Sea Salts 910.0 Lb (✓) {Typical Analysis - description attached}</p> <p>Fill and stack drums in warehouse for utilization in PharmaSea® Dead Sea Mineral Scrub product manufacturing on 02/02/01.</p> <p align="center">Grade 1 run COMPLETED -----I.</p> <p align="center">CLEAN SYSTEM THOROUGHLY</p> <p>Grade 2:</p> <p>II. Change parts for finer grade ULTRA FINE and repeat II and utilize existing setup of I with change part for finer flour like material.</p> <p align="center"><u>ADDED</u> Native Dead Sea Salts 110.00 Lb (✓) {Typical Analysis - description attached}</p> <p align="center">Grade 2 run COMPLETED -----II.</p>					
Prepared By:	Module:	Page: Of:	Section:	Page: of:	Document No.
	Milling	5 7	Bulk Milling	1 3	M001.001.00
Approved By:	Product Name:				
	Processed ULTRA FINE Dead Sea Minerals (salts)				
Lot Code: 20101AUM					

BULK MILLING-cont'd		Performed By:	Verified By:			
<p>III. <u>Reconciliation</u>: Grade 1</p> <p>a. Weigh and record: GROSS: <u>910</u> Lb</p> <p> TARE: <u>-4</u> Lb</p> <p> NET WEIGHT: <u>906</u> Lb</p> <p>Net Weight: <u>906</u> Lb x 100 = <u>99.56</u> % YIELD</p> <p> 910.0 Lb</p> <p>b. Calculate and record Milling loss:</p> <p>(<u>910</u> Lb) - (Net Weight: <u>906</u> Lb) = Milling Loss: <u>4</u> Lb</p> <p>NOTE: Yield limits are 97-103%. If outside this range, notify supervisor.</p> <p>COMPLETED -----III.</p> <p>IV. <u>Sampling</u></p> <p>a. Submit two four ounce samples to QA.</p> <p>COMPLETED -----IV.</p>				<u>MS</u>	<u>MS</u>	
Prepared By:	<u>MS</u>	Module: <u>Milling</u>	Page: <u>6</u> Of: <u>7</u>	Section: <u>Bulk Milling</u>	Page: <u>2</u> Of: <u>3</u>	Document No. <u>M001.000.01</u>
Approved By:	<u>MS</u>	Product Name: <u>Processed ULTRA FINE Dead Sea Minerals (salts)</u>	Lot Code: 20101AUM			

COMPOUNDING MODULE

ISSUED

- ☒ Preparation
- ☒ Formula Page
- ☒ Bulk Compounding


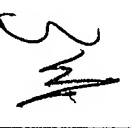


REVIEWED

- ☒ Preparation
- ☒ Formula Page
- ☒ Bulk Compounding

Issued By: Morris Samelson
Date: 02/02/01



Reviewed By: Johnathan M. Sharff
Date: 02/02/01

Prepared By: <u>M. Samelson (MS)</u>	Date: <u>02/02/01</u>	Module: <u>Compounding</u>	Page: Of: <u>1 8</u>
Approved By: <u>[Signature]</u>	Date: <u>02/02/01</u>	Product Name: <u>PharmaSea® Dead Sea Mineral Scrub</u>	



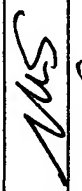

				Performed By:	Verified By:	
<p><u>PREPARATION</u></p> <p>I. <u>Equipment Required</u></p> <p>a. Primary compounding vessel: Scott Turbon Mixer (triple motion processor), 200 gal. b. Swift Heating System c. Swift Chilling System</p> <p>II. <u>Preliminary Work</u></p> <p>a. Batch DOES NOT require QA release prior to filling. Use Yellow Tank Card System.</p> <p>III. <u>Safety Precautions</u></p> <p>a. Eye protection must be worn during entire manufacturing process.</p> <p>THE ABOVE SAFETY PRECAUTIONS HAVE BEEN READ, UNDERSTOOD, SIGNED AND DATED BELOW:</p> <p><u>M. Samelson</u> <u>MS</u> <u>02/02/01</u> <u>02/02/01</u></p>						
Prepared By:		Module: Compounding	Page: 2 of 8	Section: Preparation	Page: 1 of 1	Document No. C001.001.00
Approved By:		Product Name: PharmaSea® Dead Sea Mineral Scrub				
Lot Code: 20201 (corresponds to date)						





Part Number	Description	%w/w	Control Number	Amount	Amount Weighed	Performed By:	Checked By:
	Salt Phase						
2001	Processed ULTRA FINE Dead Sea Salts	51.00		816 Lb	816	MS	MS
	Oil Phase						
1001	Palm oil	25.00		400 Lb	400	MS	MS
1002	Soybean oil	9.00		144 Lb	144	MS	MS
1003	Olive oil	5.00		80 Lb	80	MS	MS
1004	Jobba oil	3.00		48 Lb	48	MS	MS
1005	Beeswax	3.00		48 Lb	48	MS	MS
1006	Jobba wax PEG 120	1.00		16 Lb	16	MS	MS
1007	Cashew husk oil ethoxylate (Clarit)	1.00		16 Lb	16	MS	MS
1008	Coconut oil	1.00		16 Lb	16	MS	MS
1009	Vitamin E oil (Covitol 1250)	1.00		1.6 Lb	1.6	MS	MS
1010	Vitamin E oil (Covi-ox)	0.05		0.8 Lb	0.8	MS	MS
Prepared By:	MS	Module: Compounding	Page: 3	Of: 8	Section: Formula	Page: 1	Of: 2
Approved By:	MS	Product Name: PharmaSea® Dead Sea Mineral Scrub					
				Document No. C001.001.00		Lot Code: 20201	

Date of Manufacture: February 2, 2001

Prepared By: 	Module: Compounding	Page: 4	Of: 8	Section: Formula	Page: 2	Of: 2	Document No. C001.001.00
Approved By: 	Product Name: PharmaSea® Dead Sea Mineral Scrub						
Lot Code: 20201							(corresponds to date)

<u>BULK COMPOUNDING</u>				Performed By:	Verified By:			
I.	<u>Oil Phase:</u>	<div>MS</div> <div>WS</div>						
a.	Add to the Primary Compounding Vessel when temp reaches 35°C; Turn on heating system and open flow through jacket in vessel. Heat contents to 65°C while mixing slow speed.							
	Palm Oil					400 Lb	<input checked="" type="checkbox"/>	
	Beeswax					48 Lb	<input checked="" type="checkbox"/>	
	Jojoba Wax PEG 120					16 Lb	<input checked="" type="checkbox"/>	
	Beeswax					48 Lb	<input checked="" type="checkbox"/>	
	Cashew Husk Oil Exthoxylate (Clarit)	16 Lb	<input checked="" type="checkbox"/>					
Prepared By:	<div>MS</div>	Module: Compounding	Page: 5	Of: 8	Section: Bulk Compounding	Page: 1	Of: 4	Document No. C001.001.00
Approved By:	<div>WS</div>	Product Name: PharmaSea® Dead Sea Mineral Scrub						Lot Code: 20201

<u>BULK COMPOUNDING-cont'd</u>				Performed By:	Verified By:			
b. When a. reaches 65°C and is completely melted together increase mixing with high speed agitation and add:								
<div style="text-align: center;"><u>ADDED</u></div>								
Soybean oil	144.0 Lb	<input checked="" type="checkbox"/>	<div style="text-align: center;"></div>					
Olive oil	80.0 Lb	<input checked="" type="checkbox"/>						
Jojoba oil	48.0 Lb	<input checked="" type="checkbox"/>						
Covitol 1250	1.6 Lb	<input checked="" type="checkbox"/>						
Covi-ox	0.8 Lb	<input checked="" type="checkbox"/>						
Increase speed of scrape surface agitation and triple impellor to medium. Turn off heating system and close off flow of hot water to jacket of vessel. Turn on Turbon (turbine) for high speed homogeneous mixing/agitation.								
OIL PHASE COMPLETED -----I.								
II. <u>Salts Phase:</u>								
a. Add ULTRA FINE Dead Sea Salts and continue higher speed mixing:								
ULTRA FINE Dead Sea Salts		816.00 Lb	<input checked="" type="checkbox"/>	<div style="text-align: center;"></div>				
Prepared By:		Module: Compounding	Page: 6	Of: 8	Section: Bulk Compounding	Page: 2	of: 4	Document No. C001.001.00
Approved By:		Product Name: PharmaSea® Dead Sea Mineral Scrub						Lot Code: 20201

<p align="center"><u>BULK COMPOUNDING cont'd</u></p> <p>Turn on chiller system and open flow valves for chilled water. Set temperature control on jacketed process vessel to 45°C to open valves. Continue mixing with triple motion until batch temperature reaches 45°C. Continue for 15 minutes at maintained 45°C.</p> <p align="center">SALTS PHASE II. COMPLETED -----II.</p> <p>III. <u>Fragrance Phase (essential oil blend)</u> Set temperature control to 42°C and add the following once temperature of batch becomes 42°C.</p> <p>a. Combine the following in a suitable stainless steel container: <u>ADDED</u></p> <table> <tr> <td>Rosewood oil</td> <td>7.04 Lb (<input checked="" type="checkbox"/>)</td> </tr> <tr> <td>Lavender oil</td> <td>5.44 Lb (<input checked="" type="checkbox"/>)</td> </tr> <tr> <td>Chamomile oil</td> <td>3.20 Lb (<input checked="" type="checkbox"/>)</td> </tr> <tr> <td>Calendula oil</td> <td>0.32 Lb (<input checked="" type="checkbox"/>)</td> </tr> </table> <p align="center">FRAGRANCE PHASE COMPLETED -----III.</p> <p>Maintain batch at 42°C while mixing for 10 minutes. Set temperature control on jacketed process vessel to 40°C. When temperature of batch arrives at 40°C begin pumping from Scott to tube filling machine for filling tubes.</p>				Rosewood oil	7.04 Lb (<input checked="" type="checkbox"/>)	Lavender oil	5.44 Lb (<input checked="" type="checkbox"/>)	Chamomile oil	3.20 Lb (<input checked="" type="checkbox"/>)	Calendula oil	0.32 Lb (<input checked="" type="checkbox"/>)	Performed By: 	Verified By: 
Rosewood oil	7.04 Lb (<input checked="" type="checkbox"/>)												
Lavender oil	5.44 Lb (<input checked="" type="checkbox"/>)												
Chamomile oil	3.20 Lb (<input checked="" type="checkbox"/>)												
Calendula oil	0.32 Lb (<input checked="" type="checkbox"/>)												
Prepared By: 	Module: Compounding	Page: 7	Of: 8	Section: Bulk Compounding	Page: 3	Of: 4	Document No. C001,001,00						
Approved By: 	Product Name: PharmaSea® Dead Sea Mineral Scrub						Lot Code: 20201 (corresponds to date)						

		Performed By:	Verified By:
V.	<u>Reconciliation</u> <u>BULK COMPOUNDING-cont'd</u> a. Weigh and record: GROSS: <u>1600</u> Lb TARE: <u>15.62</u> Lb NET WEIGHT: <u>1584.38</u> Lb $\frac{\text{Net Weight: } 1584.38 \text{ Lb} \times 100}{1600.0 \text{ Lb}} = 99.02 \% \text{ YIELD}$ b. Calculate and record Compounding loss: (<u>1600</u> Lb) - (Net Weight: <u>1584.38</u> Lb) = Compounding Loss: <u>15.62</u> Lb NOTE: Yield limits are 97-103%. If outside this range, notify supervisor. PHASE IV. COMPLETED -----IV. VI. <u>Sampling</u> a. Submit two four ounce samples to QA. PHASE V. COMPLETED -----V.	<u>MS</u> <u>MS</u>	<u>MS</u> <u>MS</u>
Prepared By:	<u>MS</u>	Module: Compounding Page: 8 Of: 8	Section: Bulk Compounding Page: 4 Of: 4
Approved By:	<u>MS</u>	Product Name: PharmaSea® Dead Sea Mineral Scrub	Document No. C001.001.00 Lot Code: 20201 (corresponds to date)

Alan Becker

Screen Analysis

Typical Analysis

DEAD SEA BATH SALTS

אזל איהע קאמלע עניינים

Marketing Division Chemical Products

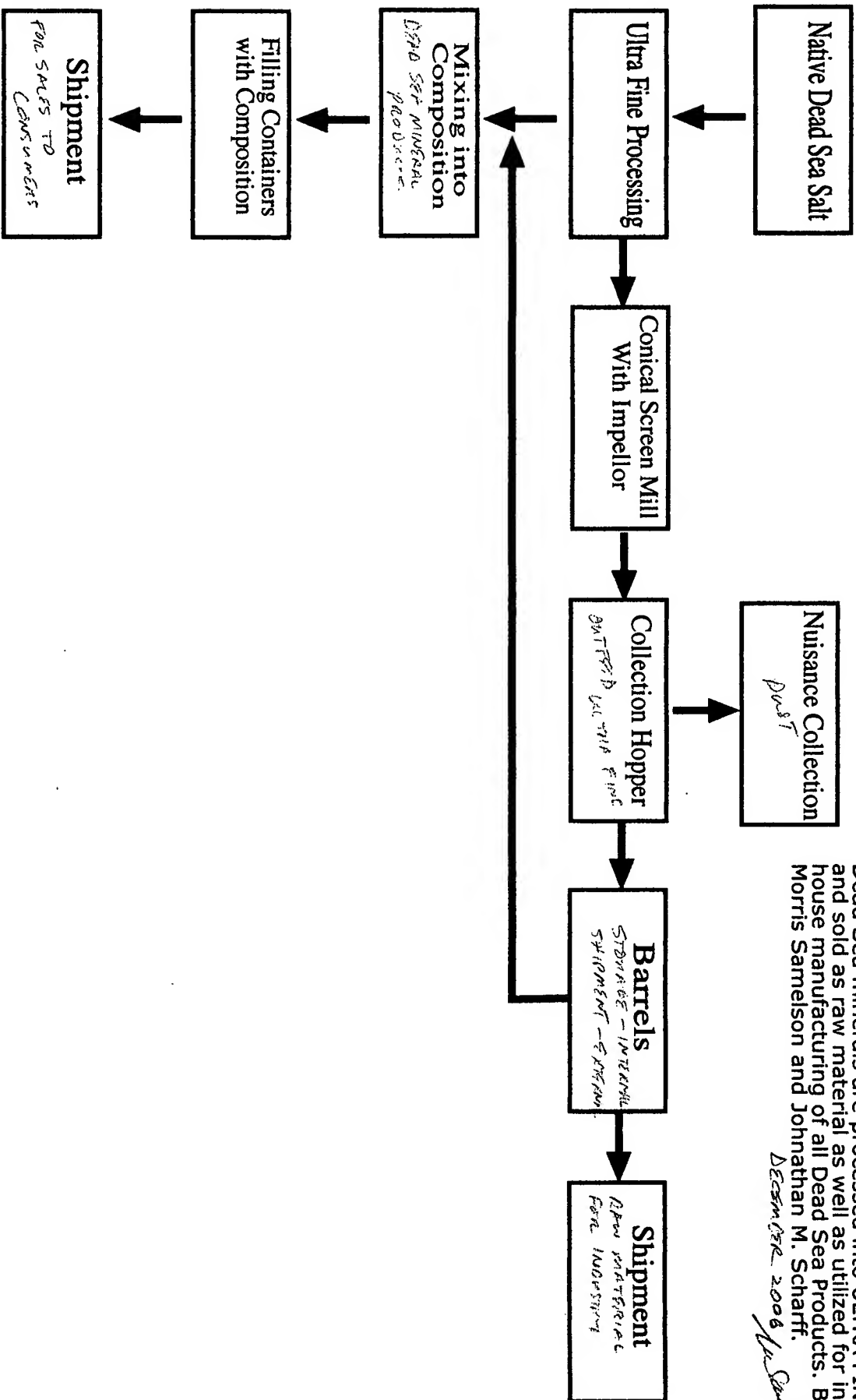
E-mail: chemerkel@dsu.co.il

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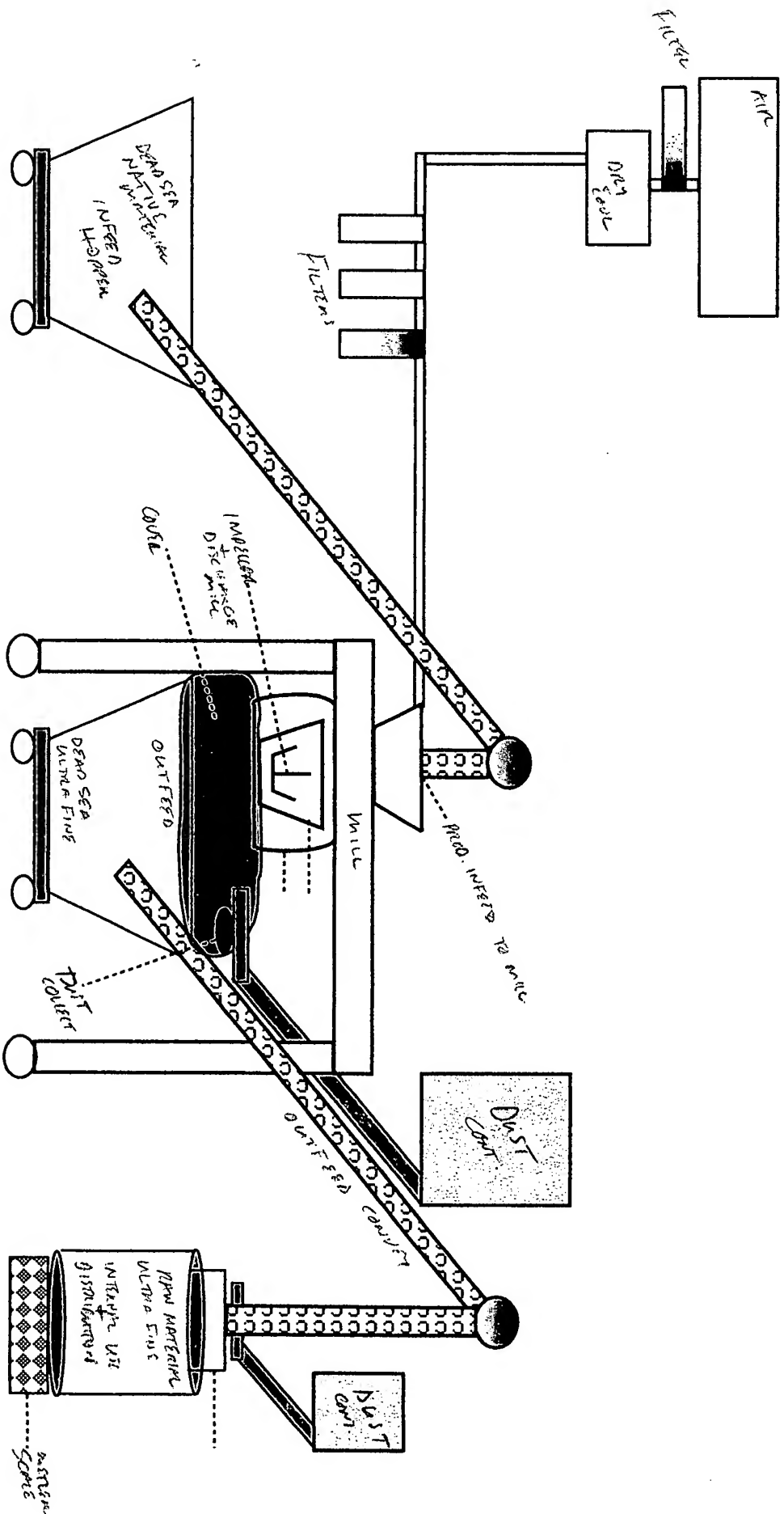
05 2455 949-20 • GDO 1550 829-20
EIL UNACE • UEL 52 • EIL-MEK 00768

GG4: 10 UG4U EX.5



FLOW CHART OF MANUFACTURING where native Dead Sea minerals are processed into ULTRA FINE and sold as raw material as well as utilized for in house manufacturing of all Dead Sea Products. By Morris Sameison and Johnathan M. Schaff. December 2006 *McSaul*

. Scharff
December 2006
McSmile



© 1997
PharmaSea®
Dead Sea Mineral Scrub



Formulated for shower, tub and sink

PharmaSea® Dead Sea Mineral Scrub

Microfine Dead Sea minerals gently exfoliate the skin. This chemical action allows the newly exposed dermal layer to absorb these minerals.

Magnesium - Assists the cellular regeneration healing process to promote cell vitality

For use in shower, tub and sink

Pharmacia Dead Sea mineral scrub gently exfoliates the skin. This cleansing action allows the newly exposed cellular layer to absorb these minerals:

- Magnesium** - Assists the cellular regeneration healing process to promote cell vitality
- Calcium** - Helps cell membranes absorb vital nutrients
- Chlorine** - Regulates cell moisture levels
- Calcium & Sodium** - Facilitates mineral balance within the cell and enhances cell function and metabolism
- Ammonium & Sulfates** - Acts as natural cleanser and soothing antiseptic

Exfoliated skin is simultaneously treated with a unique combination of rich emollient oils that soothe and moisturize. Skin is more supple and smoother to the touch immediately after use.

This 2 combination therapy is your ultimate source for anti-aging and skin therapy. Absolutely no Petroleum Distillates.

(Skin may be wet or dry prior to application)

Directions:

Dry Skin: Apply a liberal amount onto palms and gently massage. Pay particular attention to dry or rough areas. Wait 1 to 2 minutes. Rinse thoroughly with warm water. Towel dry thoroughly. For eczema, psoriasis, eczema, excessive dryness: Follow general directions. Use on skin surface 3 to 5 minutes. Use at least three times a week. For best results, use with Pharmacia Dead Sea Bath Salts for cellular therapy.

Ingredients: Dead Sea Minerals, Palm Oil, Soybean Oil, Jojoba Oil, Beeswax, Coconut Oil, Jojoba Wax, Peppermint Oil, Eucalyptus Oil, Eucalyptol, Rosewood Oil, Lavender Oil, Chamomile Oil, Vitamin E Oil, Calendula Oil.

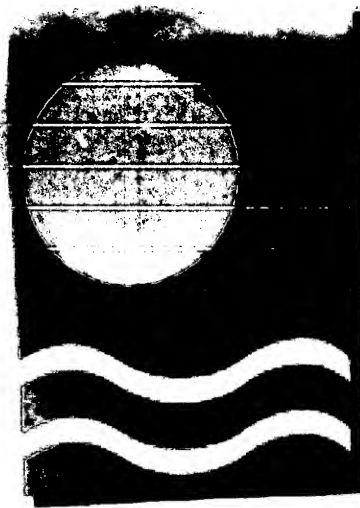
Pharmacia Dead Sea Mineral Scrub
Part of the consumer products division of:

Pharmacia International Inc.
San Antonio, TX
www.Pharmacia.com

No Testing

**Doctor
Recommended!**

Dead Sea Mineral Scrub



PharmaSea®

*Life Enhancing Minerals Harvested
From Nature's Pharmacy™*

*Advanced Dead Sea Therapy™
for ultimate skin
care & health.*

100% Natural

Exfoliates

•
Nourishes

•
Rejuvenates

Net Weight - 5 oz.